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(58) Field of Search

UK CL (Edition R) A5G GAA, G5C CAD CAX CBL CBM  
CFX

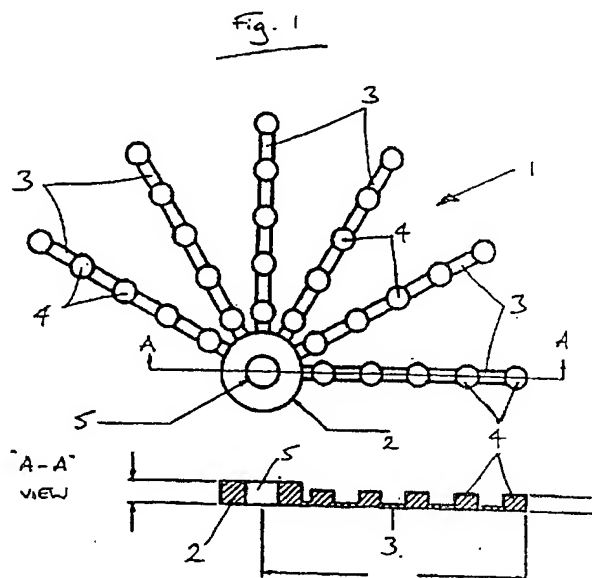
INT CL<sup>7</sup> A61L 2/26, G09F 3/00 3/02 19/00

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(54) Abstract Title

Indicating tag to show the number of uses a piece of apparatus has undergone

(57) An indicating tag 1 adapted to be secured to an apparatus for indicating the number of uses the apparatus has undergone comprises a body portion 2 from which one or more limbs 3 extend, each limb having one or more elements 4 thereon. One element may be removed from the tag following each use of the apparatus to which the tag is secured. The tag may comprise N elements, N being the number of permitted uses of the apparatus. The apparatus may be a surgical apparatus and the uses sterilisation cycles, in which case the tag may be made from a mouldable material which retains its shape when subjected to a sterilisation cycle, e.g. a thermoplastic elastomer or silicon rubber.



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Fig. 1

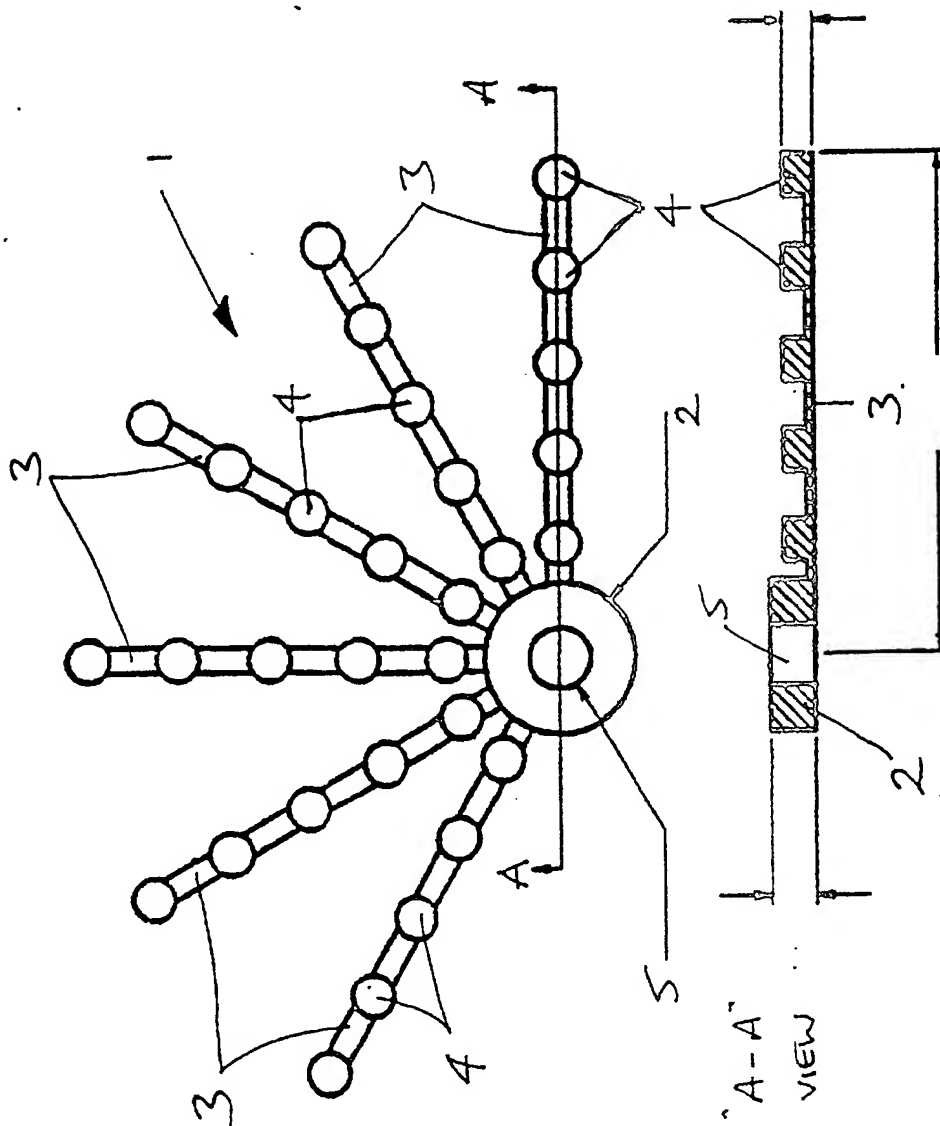
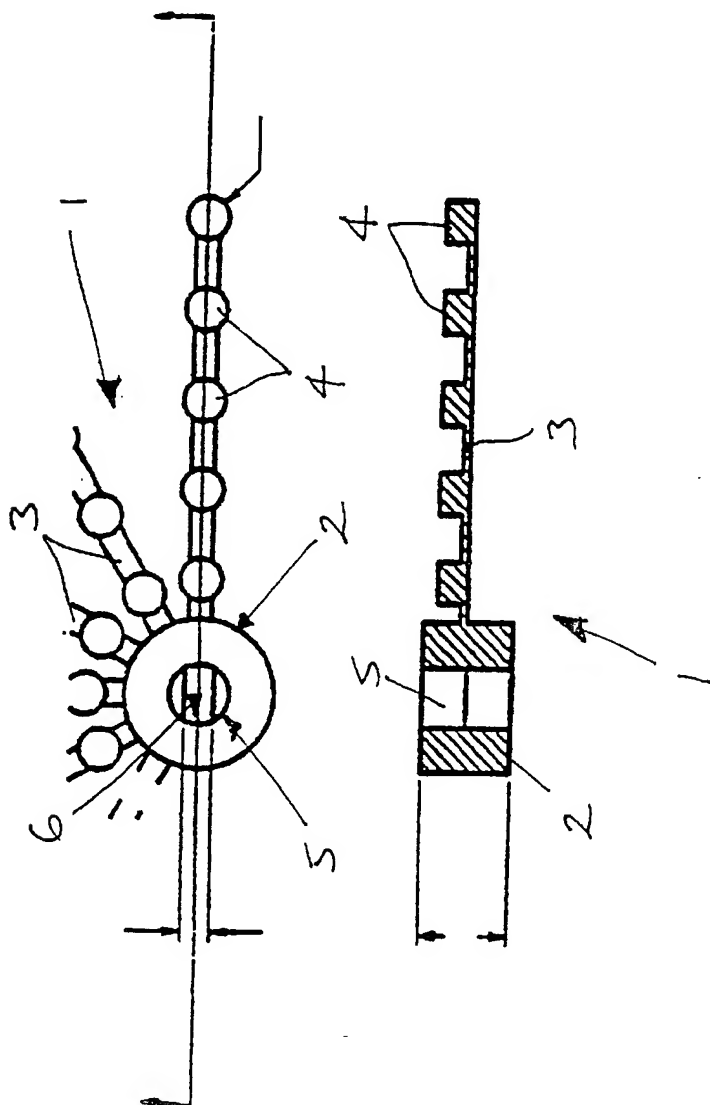


Fig. 2



1     **STERILISATION CYCLE INDICATOR TAG**

2

3     The present invention relates to indication means for  
4     use in monitoring cycles of treatment experienced by an  
5     item of apparatus. In particular the present invention  
6     relates to a tag for use in monitoring the number of  
7     cycles of sterilisation treatment to which an item of  
8     surgical apparatus is subjected.

9

10    In surgical operating theatres, electrical cables are  
11    required for the powering of surgical and monitoring  
12    equipment. In addition, high-frequency electrical  
13    currents are required in a number of surgical  
14    procedures in the surgical area of the theatre. One  
15    such procedure is diathermy, where an electrical  
16    current is used on a patient in order to produce  
17    coagulation or necrosis of skin cells.

18

19    As with all equipment that is used in the surgical  
20    area, the cables carrying these currents are required  
21    to be sterile. Thus, after each use, the cables are  
22    put through a sterilisation cycle in order to be  
23    sterilised. For sterilisation, the sterilising cycles  
24    commonly use either high energy ionising radiation,  
25    steam autoclaving, or ethylene oxide exposure on the

1 cables. With any of these sterilisation cycles,  
2 degradation of the cable will occur. Thus, the cables  
3 may only be used for a certain number of cycles before  
4 they fail, and a new cable is required.

5  
6 However, using a cable to failure is a hazardous  
7 practice, as it is common for the person using the  
8 cable to receive a painful burn from the spark produced  
9 when the cable fails. As a precaution, therefore,  
10 cable manufacturers only recommend that their cables be  
11 used for a particular number of cycles before they  
12 should be replaced. In practice, however, it has so  
13 far proved difficult and inconvenient for surgical  
14 staff to record each cycle that a cable is put through.

15  
16 A number of methods have been suggested for keeping  
17 track of the number of cycles that cables have been  
18 through. In theory, a straightforward method would be  
19 to assign each individual cable a code number in the  
20 manufacturing process. The surgical staff would then  
21 note each time they sterilised a particular cable. In  
22 practice, however, staff would find this hugely  
23 impractical to record each cycle on a daily basis. A  
24 simpler method would be to print a dot or mark on the  
25 cable. This mark would then diminish after every cycle  
26 until it disappeared entirely, and the cable would then  
27 be thrown away. This method is particularly inexact,  
28 as there would be no way of knowing the exact number of  
29 cycles the cable had been through.

30  
31 It is therefore the aim of the present invention to  
32 provide a simple, straightforward, and practical  
33 indication means that can show exactly how many times a  
34 cable or other item of surgical apparatus has been  
35 sterilised. Thus, the cable may be discarded after the  
36 manufacturer's recommended number of cycles is reached

1 without any ambiguity, and without any risk of injury  
2 to those who come into contact with the degraded  
3 cables.

4  
5 According to a first aspect of the present invention,  
6 there is provided an indicating tag adapted to be  
7 secured to an apparatus in which the number of uses of  
8 said apparatus must be monitored, wherein said  
9 indicating tag comprises a body portion and one or more  
10 limbs extending from said body portion, each of said  
11 limbs having one or more elements thereon, said  
12 elements being arranged such that an element may be  
13 removed from said tag following each use of the  
14 apparatus to which the tag is secured.

15  
16 Preferably, the apparatus is a surgical apparatus and  
17 the use is a sterilisation cycle.

18  
19 Preferably the tag has N elements where N is the number  
20 of permitted uses of the apparatus.

21  
22 Preferably the tag comprises a plurality of limbs.  
23 Preferably each limb has a plurality of elements  
24 thereon. Preferably each limb is an elongate member.  
25 Preferably said elements comprise thickened portions of  
26 said limb arranged longitudinally along said elongate  
27 member.

28  
29 Preferably, said limb comprises a substantially  
30 cylindrical member having a first diameter or a flat  
31 member having a first thickness. Preferably, each  
32 element comprises a substantially spherical portion  
33 having a second diameter greater than said first  
34 diameter or thickness. Alternatively each element may  
35 comprise a disc shaped portion or a block shaped  
36 portion having an overall transverse dimension greater

1     than said first diameter or first thickness.

2

3     Preferably said tag is made from a mouldable material  
4     which retains its physical shape when subjected to  
5     sterilisation. Preferably, said tag is made from a  
6     thermoplastic elastomer material such as Santoprene®.  
7     Alternatively, said tag is made from silicon rubber.

8

9     Preferably, said tag further comprises fastening means  
10    for attaching said tag to the apparatus. The fastening  
11    means may comprise male and female cable tie members,  
12    an aperture adapted to surround a portion of the  
13    apparatus, or other suitable fastening means.

14

15    According to a second aspect of the present invention,  
16    there is provided a method for counting the number of  
17    uses of an apparatus, said method comprising attaching  
18    a tag according to the first aspect of the present  
19    invention to an apparatus,  
20    wherein the tag has N elements where N is the number of  
21    permitted uses of the apparatus, and  
22    wherein one of the elements is removed from said tag  
23    each time the apparatus is used, such that no elements  
24    remain on the tag after N uses.

25

26    Preferred embodiments of the present invention will now  
27    be described, by way of example only, with reference to  
28    the following drawings, in which:

29

30           Figure 1 shows plan and cross-sectional views of a  
31           first embodiment of the present invention.

32

33           Figure 2 shows plan and cross-sectional views of a  
34           detail of a second embodiment of the present  
35           invention.

36

1 Figure 1 shows an indicating tag 1 in accordance with  
2 the present invention. The indicating tag 1 of Figure  
3 1 is intended for use in conjunction with cables in  
4 operating theatres, where said cables must be  
5 sterilised after each use. As discussed above, the  
6 cables degrade after each sterilisation cycle, and as a  
7 precaution manufacturers recommend a maximum number of  
8 cycles before the cable should be replaced.

9  
10 The indicating tag 1 has a cylindrical body portion 2  
11 from which extend a number of limbs 3, and  
12 equidistantly spaced along the length of each limb 3  
13 are a number of protruding portions or dimples 4. The  
14 number of limbs 3 and the number of dimples 4 on each  
15 limb 3 is dictated by the number of cycles that the  
16 manufacturer of the cables recommends should not be  
17 exceeded. For example, if it is recommended that a  
18 cable should not be subjected to more than forty  
19 sterilisation cycles, then eight limbs 3 with five  
20 dimples 4 on each limb 3 would be provided around the  
21 circumference of the cylindrical body 2.

22  
23 The aim of the present invention is to provide very  
24 simple means with which to monitor the number of cycles  
25 that a piece of equipment - in this example, cables -  
26 has been through. After each cycle, the operator who  
27 has sterilised the cable simply takes a pair of  
28 scissors or the like, and removes the outermost dimple  
29 4 from one of the limbs 3. Alternatively the limbs may  
30 be thin enough to allow a dimple to be removed by hand  
31 by pulling the end dimple. This process is repeated  
32 after each cycle until such time as there are no  
33 dimples 4 or, as a consequence, limbs 3 remaining.  
34 Once the final dimple 4 has been removed, this then  
35 tells the operator that the cable has been sterilised  
36 the recommended number of times, and that it should now



1 be discarded and replaced by a new cable.

2

3 Figure 1 shows an embodiment of the present invention  
4 where the centre aperture 5 of the cylindrical body 2  
5 is circular to accommodate a standard single cable.

6 Figure 2, however, shows a second embodiment of the  
7 present invention wherein the indicating means 1 has a  
8 modified centre aperture 5. The aperture 5 has been  
9 modified into the shape of a slot 6, so that dual  
10 cables can be accommodated and held securely by the  
11 aperture 5.

12

13 In the preferred embodiments of the present invention,  
14 the indicating means 1 is manufactured from the  
15 thermoplastic elastomer Santoprene® and moulded in one  
16 piece. Santoprene® is produced by Advanced Elastomer  
17 Systems and has a wide variety of uses in the medical  
18 products field. Santoprene® benefits from having the  
19 same properties as a conventional thermoset rubber  
20 allied to the easy processability of a thermoplastic.  
21 In addition, as Santoprene® is totally synthetic and  
22 not derived from natural rubber, it is free from the  
23 problems associated with natural rubber in medical  
24 applications, such as allergic reactions and the like.

25

26 Although Santoprene® is the preferred material from  
27 which to produce the present invention, other materials  
28 may be used. For example, silicon rubber shares  
29 similar properties to Santoprene®.

30

31 Other modifications and improvements may be  
32 incorporated without departing from the scope of the  
33 present invention. For example, the present invention  
34 need not only be used in conjunction with cables. As  
35 well as other medical apparatus such as laryngeal  
36 masks, for example, the present invention could be used

1 with any equipment in which the number of uses of said  
2 equipment must be monitored. The means of attachment  
3 may be a cable tie instead of an aperture. This would  
4 enable the tag to be put on a cable after the end plugs  
5 have been attached to the cable. Other means of  
6 attachment are possible, such as riveting, bolting,  
7 clamping, adhesives etc.

8  
9 The shape of the tag is not limited to that shown in  
10 the drawings. Although the drawings show disc shaped  
11 protruding elements, these may be spheres, cuboid  
12 blocks, rods or other polygonal shapes.

13  
14 These and other modifications and improvements can be  
15 incorporated without departing from the scope of the  
16 invention.

1     **CLAIMS:**

2

3     1.    An indicating tag adapted to be secured to an  
4    apparatus in which the number of uses of said apparatus  
5    must be monitored, wherein said indicating tag  
6    comprises a body portion and one or more limbs  
7    extending from said body portion, each of said limbs  
8    having one or more elements thereon, said elements  
9    being arranged such that an element may be removed from  
10   said tag following each use of the apparatus to which  
11   the tag is secured.

12

13   2.    An indication tag according to Claim 1, wherein  
14   said tag has N elements where N is the number of  
15   permitted uses of the apparatus.

16

17   3.    An indicating tag according to either Claim 1 or  
18   Claim 2, wherein said tag comprises a plurality of  
19   limbs.

20

21   4.    An indicating tag according to Claim 3, wherein  
22   each of said plurality of limbs has a plurality of  
23   elements thereon.

24

25   5.    An indicating tag according to any preceding  
26   claim, wherein each of said one or more limbs is an  
27   elongate member.

28

29   6.    An indicating tag according to Claim 5, wherein  
30   each of said one or more elements comprise thickened  
31   portions of said limb arranged longitudinally along  
32   said elongate member.

33

34   7.    An indicating tag according to any preceding  
35   claim, wherein said apparatus is a surgical apparatus  
36   and the use is a sterilisation cycle.

1     8.   An indicating tag according to Claim 7, wherein  
2     said tag is made from a mouldable material which  
3     retains its physical shape when subjected to the  
4     sterilisation cycle.

5  
6     9.   An indicating tag according to Claim 8, wherein  
7     said tag is made from a thermoplastic elastomer  
8     material.

9  
10    10.  An indicating tag according to Claim 8, wherein  
11    said tag is made from silicon rubber.

12  
13    11.  An indicating tag according to any preceding  
14    claim, wherein said tag further comprises fastening  
15    means for attaching said tag to the apparatus.

16  
17    12.  An indicating tag according to Claim 11, wherein  
18    said fastening means comprises male and female cable  
19    tie members.

20  
21    13.  An indicating tag according to Claim 11, wherein  
22    said fastening means comprises an aperture adapted to  
23    surround a portion of the apparatus.

24  
25    14.  A method for counting the number of uses of an  
26    apparatus, said method comprising attaching a tag  
27    according to any of Claims 1 to 13 to an apparatus,  
28    wherein the tag has N elements where N is the number of  
29    permitted uses of the apparatus, and  
30    wherein one of the elements is removed from said tag  
31    each time the apparatus is used, such that no elements  
32    remain on the tag after N uses.

33  
34    15.  An indicating tag as substantially hereinbefore  
35    described and illustrated in the accompanying drawings.

36

- 1 16. A method for counting the number of uses of an
- 2 apparatus as substantially hereinbefore described.



Application No: GB 9921450.4  
Claims searched: 1-16

Examiner: Annabel Ovens  
Date of search: 4 February 2000

**Patents Act 1977**  
**Search Report under Section 17**

**Databases searched:**

UK Patent Office collections, including GB, EP, WO & US patent specifications, in:

UK Cl (Ed.R): G5C (CAD, CAX, CBL, CBM, CFX), A5G (GAA)

Int Cl (Ed.7): A61L (2/26), G09F (3/00, 3/02, 19/00)

Other: Online: PAJ, EPODOC, WPI

**Documents considered to be relevant:**

Category	Identity of document and relevant passage		Relevant to claims
X, Y	WO 97/04644	(SERIEYS) see page 2 lines 13-18 and 27-31, page 4 lines 5-6 and Fig.	X: 1, 2, 5, 11 and 14 Y: 6
X	WO 95/14375	(LOGAN) see page 1 lines 16-20 and 28-33, page 2 lines 22-27 and Fig.	1, 2 and 11, 12 and 14
Y	US 3556291	(SEBRING) see column 2 lines 53-58 and Figs. 4 and 5	6

X Document indicating lack of novelty or inventive step  
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